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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,164	10/16/2003	Chih-Hung Lee	7031.US01	6816

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EXAMINER	
DAVIS, ZINNA NORTHINGTON	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,164	LEE ET AL.	
	Examiner	Art Unit	
	Zinna Northington Davis	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on ____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *13-17 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,9,10,12 and 18* is/are rejected.

7)☒ Claim(s) *4-6,8 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2/04* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

5.00

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 and 18, drawn to a chemical compound and a pharmaceutical composition wherein X is CH; Y is CH; and L is $-C(O)N(R_3)-$.

II. Claims 1 and 13-17, drawn to a chemical compound and a pharmaceutical composition other than a compound of Group I.

III. Claims 19-23, drawn to a method of treating using a compound I of Group I.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. See claims 20-22.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: see the radical s as defined by A, X, L, and Y.

Applicant has been required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-18 are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Applicant's Representative on June 3, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12 and 18, the species where X is CH; Y is CH and L is $-C(O)N(R_3)-$. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-17 and 19-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Claims 1-12 and 18 are Markush claims, which are generic to the elected invention. These Markush claims lack unity of invention. Accordingly, the Markush type

claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

7. Claims 1-12 and 18 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnisch, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are A, X, L, and Y.

8. The examined subject matter is as follows:

A compound of formula (I) wherein X is CH; Y is CH and L is -C(O)N(R_3)-. All other radicals are defined as in claim 1. Amending the claims to the examined subject matter would overcome the improper Markush objection.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Doyle et al (Reference A).

The instantly claimed compound is disclosed. At page 17, 1st column, lines 48 and 49, see the named compound.

11. Claims 1-3, 7, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Glaxo Group Limited (Reference N).

The instantly claimed compounds are disclosed. At page 3, see the generic compound of formula (I). At page 26, line 34, see Example 8.

12. Claims 1-3, 7, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rotta Research Laboratorium (Reference O).

The instantly claimed compound is disclosed. At page 2, lines 3-4, see the named compound.

13. Claims 1, 12, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Millennium Pharmaceuticals (Reference P)

The instantly claimed compound is disclosed. At pages 49 and 50, line 2, see compound AV.

14. Claims 1, 3, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shionogi and Co., Ltd (Reference Q)

The instantly claimed compound is disclosed. At page 20, 2nd column, see compound Ib-23.

15. Claims 1-3, 9, 10, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Novo Nordisk A/S (Reference R)

The instantly claimed compounds are disclosed. At pages 224 and 225, lines 1-3, see Example 502. At pages 225, lines 15-20, see Example 505.

16. Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Basha et al (Reference U).

The instantly claimed compound is disclosed. At pages 306, 2nd column, Table 1, see the 3rd named compound.

17. Claims 1-3 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fujisawa Pharmaceutical Co., Ltd (Reference V).

The instantly claimed compounds are disclosed. See the generic compound of formula I. See RN 252927-75-6 and RN 252928-26-0.

18. Claims 4-6, 8, and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

19. The Information Disclosure Statements filed February 11, 2004 has been considered.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna N. Davis whose telephone number is 571-272-0682.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Znd
05.30.2005

ZINNA NORTHINGTON DAVIS
PRIMARY EXAMINER